

Serial No. 10/070,084
Docket No. PU3517USw
Reply to Office Action of December 16, 2004

Remarks

Applicants note with appreciation the courtesy of a telephonic interview extended by the Examiner to Applicants' attorney. Applicants also note with appreciation the allowance of Claims 23, 25, and 55. Claims 2-7, 9-14, 18-20, 23, 25, 26, 28, 29, 34-36, 40, 43-51 and 54-62 are pending. Claims 2, 18, 26, 40, 43-49 and 61 are currently amended. No new matter is presented by way of these amendments.

Claim 18 stands rejected under 35 U.S.C. § 112, as failing to comply with the written description requirement. Claim 18 has been amended to correct a typographical error. This rejection is now moot.

Claims 28, 29, 48, 49, 50 and 51 stand rejected under 35 U.S.C. § 112, first paragraph, because the Examiner contends that the specification "does not reasonably provide enablement for a method of treatment of HIV infection generally or a method of inhibiting HIV reverse transcriptase generally. The Examiner does acknowledge that the claims are enabling for treatment of HIV-1.

Applicants respectfully disagree with the Examiner's contention that claims 28, 29, 48, 49, 50 and 51 are not enabled for treatment of HIV infection generally. Doses, modes of administration, and pharmaceutical formulations can be found in the specification at pages 63-67. Applicants have shown that the compounds of the present invention inhibit HIV replication in a cell-based assay as demonstrated in Table 1. Further, Table 1 provides data against both HIV-1 and HIV-2 viruses in a cell-based assay. Representative compounds across the scope of the claimed invention were tested and results are provided in Table 1. Further, doses, modes of administration and pharmaceutical formulations can be found in the specification at pages 63-67. Regarding the treatment of HIV, generally, there are several HIV drugs on the market today, including Retrovir®, Combivir®, Epivir®. Accordingly, there is precedent for use of antiretroviral agents in the treatment or prevention of HIV infection. For example, Retrovir® (zidovudine) is a reverse transcriptase inhibitor that is indicated for treatment of HIV, in addition to the prevention of maternal-fetal transmission of HIV (see Retrovir® (zidovudine) prescribing information, page 8, April, 2003, copy enclosed).

Additionally, regarding the "state of the art" references cited by the Office, the Office has failed to read the articles as a whole. For example, the HIV Guidelines (cite 1), in the same paragraph quoted by the Office, provides, "[i]n the United States and Europe, individuals infected with HIV-2 receive the same treatments as those infected with HIV-1." It

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further provides, "[t]reatments for opportunistic infections and cancers are the same, whether they are caused by HIV-1 or HIV-2 infection." Regarding the second document cited by the Examiner (cite 2), it is directed to a completely different class of compounds, wholly unrelated to Applicants' invention.

Applicants have shown activity against both HIV-1 and HIV-2 by compound of the invention and provided sufficient dosage, routes of administration and pharmaceutical formulations. Because the specification teaches how to use the compounds of the invention and because HIV reverse transcriptase inhibitors may be used to treat or prevent HIV infection, Applicants respectfully request the withdrawal of the rejection of claims 28, 29, 48, 49, 50 and 51 under 35 U.S.C. § 112, first paragraph.

Claims 2 - 7, 9 - 14, 18 - 20, 26, 28, 29, 34 - 36, 40, 43-51, 54 and 56 - 62 are rejected under 35 U.S.C. § 112, second paragraph. Applicants respectfully traverse and submit the following:

1. One of ordinary skill in the art would understand the term " $-SR^{10}N(R^{10})_2$ " as written. As provided in claims 2 and 12, and as one of ordinary skill in the art would readily understand, if R^{10} is C_{1-8} alkyl, the R^{10} group connecting, or between, $-S$ and $-N(R^{10})_2$ is a bivalent alkyl and the two R^{10} groups at the end, or attached to the nitrogen atom are monovalent. One of ordinary skill in the art would easily understand the term based upon the claims and further in light of the description in the specification as well as the examples provided throughout the specification.

2. Claim 2 has been amended to correct the typographical error. Accordingly, this rejection is moot.

3. As one of ordinary skill in the art understands, it is well known that open valencies are filled by hydrogen, unless specified otherwise. It is not common practice in the field of organic chemistry to provide all hydrogen atoms in written formulae. The common practice is to omit hydrogen atoms where one of skill in the art would understand that such a hydrogen atom would complete any open valencies. Applicants have simply chosen to follow common organic chemistry practice and not provide hydrogen atoms to fill all empty valencies. It is therefore not necessary for Applicants to provide all hydrogen atoms in each and every written formula as suggested by the Office.

4. As stated above, one of ordinary skill in the art understands that is common practice that, unless specified otherwise, open valencies are filled by H. The numerous examples provided in the specification further support this position.

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5. One of ordinary skill in the art would easily understand the difference between a monovalent alkyl and a bivalent alkyl based upon the formula as written. As stated above, one of ordinary skill in the art would understand that, as shown in the examples, if R¹¹ is an alkyl, then the R¹¹ connecting, or between -O and -OR¹¹ is a bivalent group. As previously indicated, an illustration of the term "-OR¹¹OR¹¹" is provided by Examples 250, 251, and 252 on pages 359 - 361.

6. Claim 18 has been amended to correct a typographical error. Therefore, this rejection is moot.

7. Claims 26 and 43-47 have been amended to remove "particularly". Accordingly, this rejection is moot.

8. Claim 40 has been amended to delete the term "R³". Accordingly, this rejection is moot.

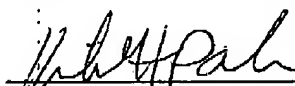
9. Claim 48 and 49 have been amended, therefore, this rejection is moot.

Examiner's points 1 through 9 having been addressed, Applicants respectfully request withdrawal of the rejection of claims 2 - 7, 9 - 14, 18 - 20, 26, 28, 29, 34 - 36, 40, 43-51, 54 and 56 - 62 under 35 U.S.C. § 112, second paragraph.

In view of the amendments and foregoing discussion, it is respectfully submitted that the present application is in condition for allowance. An early consideration and notice of allowance are earnestly solicited.

The Commissioner is hereby authorized to charge any fees required or credit any overpayment to Deposit Account No. 07-1392.

Respectfully submitted,



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